REMARKS

Claims 1-5, 7-14, 16-23, 25-28, and 30 are pending. Claims 1, 10, 19, 20, 25, and 30 have been amended. Claims 1-5, 7-14, 16-23, 25-28, and 30 remain in the case. No new matter has been introduced.

In response to the final Office action mailed on September 24, 2003, a Notice of Appeal was filed by facsimile on January 24, 2004. Pursuant to 37 CFR 1.114(d), applicant requests that the appeal be withdrawn and that prosecution before the examiner be reopened. The request for continued examination includes amendments to the written description and claims, an IDS submitting additional references, and new arguments in satisfaction of the submission requirement pursuant to 37 C.F.R. 1.114(c). Applicant requests withdrawal of the final Office action and a non-final first Office action. 37 C.F.R. § 1.114(d); MPEP 706.07(b).

An Information Disclosure Statement citing further art references was filed on September 22, 2003, prior to the mailing date of a final action under 37 C.F.R. 1.113. The Information Disclosure Statement must be considered on the record. 37 C.F.R. 1.97(c). An additional Information Disclosure Statement citing additional further art references is provided pursuant to 37 C.F.R. 1.114(c). Acknowledgement of the Information Disclosure Statements and entry of the cited art references is requested.

Preliminarily, Claims 1, 10, 19, 20, 25, and 30 have been amended to address the 35 U.S.C. 112, first and second paragraph rejections and to present the rejected claims in better form for consideration on appeal. No claim has been amended in response to the 35 U.S.C. 102(e) and 35 U.S.C. 103(a) rejections. The amendments do not touch on the merits, so the amendments may be admitted without a showing of good and sufficient reasons why the amendments were necessary and were not earlier presented. 37 C.F.R. 1.116. The claim amendments were presented in the earlier application after final rejection but were denied entry because new issues were raised that potentially required further consideration or search. MPEP 706.07(b).

Claims 1, 10, 19, 20, 25, and 30 are amended to address the 35 U.S.C. 112, first and second paragraph rejections. No claim has been amended in

response to the 35 U.S.C. 102(e) and 35 U.S.C. 103(a) rejections. Entry of the amendment to Claims 1, 10, 19, 20, 25, and 30 is requested.

Claims 1-5, 7-14, 16-23, 25-28 and 30 stand rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. Claims 1, 10, 20, and 25 have been amended to comply with the written description requirement. Withdrawal of the rejection under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement is requested.

Claims 1-5, 7-14, 16-23, 25-28 and 30 stand rejected under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement. Claims 1, 10, 20, and 25 have been amended to comply with the enablement requirement. Withdrawal of the rejection under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement is requested.

Claims 19 and 30 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite. The claims 19 and 30 have been amended to delete the references to canceled claims. Withdrawal of the rejection under 35 U.S.C. 112, second paragraph is requested.

Claims 1-5 and 10-14 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,155,267, to Nelson. Applicant traverses the rejection. The Nelson reference fails to describe, either expressly or inherently, each and every claim element of, and therefore does not anticipate, Claims 1-5 and 10-14.

Nelson discloses an implantable medical device and monitoring method providing at least one sensor output signal to the implantable medical device and chronic data representative of at least one physiological parameter (Abstract). A baseline is established using the chronic data provided over an initial sample time period (Col. 2, lines 57-59). The chronic data is then monitored to detect a change in state of the physiological parameter relative to the baseline (Col. 2, lines 52-64). Data associated with detected changes in state is stored within the implantable medical device (Col. 4, lines 53-59). Only detected changes in state are recorded and the chronic data received by the monitoring device is discarded

(Col. 4, lines 59-61)

Nelson fails to describe, teach or suggest each and every claim element of Claims 1 and 10. Specifically, Nelson fails to teach or suggest measuring qualitative values, such as quality of life measures recorded by the individual patient. Instead, Nelson teaches monitoring quantitative chronic data, such as from an oxygen sensor and a pressure sensor (Col. 10, lines 28-42). As well, Nelson fails to teach or suggest storing one or more reference or updated physiological measures and one or more reference or updated quality of life measures into a patient care record. Moreover, Nelson fails to teach or suggest comparing updated physiological and quality of life measures respectively to reference physiological and quality of life measures. Therefore, the Nelson reference fails to describe all the claim limitations and does not anticipate Claims 1 and 10.

Claims 2-5 are dependent on Claim 1 and are patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Similarly, Claims 11-14 are dependent on Claim 10 and are patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Accordingly, the Nelson reference fails to describe, either expressly or inherently, each and every claim element of Claims 1-5 and 10-14. As Nelson fails to anticipate Claims 1-5 and 10-14, withdrawal of the rejection for anticipation under 35 U.S.C. 102(e) is requested.

Claims 1-5, 10-14, 20-23 and 25-28 stand rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,724,983, to Selker et al (Selker I), in view of U.S. Patent No. 5,603,331, to Heemels et al, and further in view of U.S. Patent No. 6,168,563, to Brown. To establish a *prima facie* case of obviousness: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine the reference teachings; (2) there must be a reasonable expectation of success; and (3) the combined references must teach or suggest all the claim limitations. MPEP § 2143. Applicant traverses the rejection.

The Selker I, Heemels, and Brown patents, taken as a whole, do not provide a suggestion, motivation, or reason to combine. Additionally, even when combined by picking and choosing selected parts, the Selker I, Heemels, and Brown patents do not teach or suggest all claim limitations when considered in light of the disclosure of each respective patent. Finally, if combined, the Selker I, Heemels, and Brown patents do not provide a reasonable expectation of success.

Selker I teaches continuous monitoring using a predictive instrument, preferably by computing a probability of a medical outcome or diagnosis, such as an acute cardiac ischemia, based on monitored clinical features (Col. 1, line 61-Col. 2, line 3). The Selker I device is preferably embodied as a cardiac patient monitoring system, which includes a 12-lead electrocardiograph, waveform analyzer, predictive instrument, and control module (Col. 2, lines 49-52). The waveform analyzer is programmed to analyze ECG waveforms, such as S-T segments, Q waves, and T waves, and to recognize the presence of certain characteristics that are particularly indicative of a cardiac condition (Col. 2, lines 54-60). The device can be programmed to identify the location of a myocardial infarction and can compute the probability that the patient has an acute (sudden) cardiac ischemia (Col. 3, lines 30-42; Col. 4, lines 14-17). Prediction and notification is based on the control module calculations that compare the computed changed statistic to a first threshold, which is an alarm threshold (Col. 4, lines 45-50). Data storage is limited to probabilities above a second threshold (Col. 5, lines 8-18). Finally, Selker I can periodically compute and monitor for changes to any probability of a serious cardiac condition, in addition to the probability of an acute cardiac ischemia (Col. 8, lines 16-28).

Heemels teaches an implantable cardiac rhythm management device for processing and storing the volume of heart rate variability data (Abstract). An implantable stimulator, such as a pacemaker, defibrillator or monitoring device, processes and logs multiple sets of two-dimensional histogram data for sensed beat intervals, which are retained for subsequent retrieval via telemetry (Col. 3, lines 9-26). A logarithmic compression algorithm is used to compress the collected data to conserve data memory, processor memory, and power

consumption on the implantable stimulator (Col. 2, lines 26-33; Col. 3, lines 1-8). An external programmer may then develop a presentation of the data, including individual or composite histograms (Col. 3, lines 26-30). Data collection is limited to a 24-hour period (Col. 2, lines 28-31).

Brown teaches a system and method for monitoring and managing a health condition of a patient by using a remotely programmable patient-operable apparatus (Abstract). The programmable patient apparatus provides information to the patient about the patient's health condition and interactively monitors the patient health condition by asking the patient questions and by receiving answers to those questions (Col. 14, line 27-Col. 15, line 16). The patient information may include information supplied by a physiological monitoring device, such as a blood glucose monitor or peak-flow meter, that is physically connected to the remotely programmable patient apparatus (Col. 11, lines 26-61; Col. 15, lines 40-57). However, the physiological monitoring device must provide the data in a serial format in synchronization with clock signals provided by the programmable patient apparatus (Col. 11, lines 61-66).

A *prima facie* case of obviousness has not been shown. First, the Selker I, Heemels, and Brown patents, taken as a whole, do not provide a suggestion, motivation, or reason to combine. Selker I would not reasonably be combined with Heemels or Brown when considering the disclosures as a whole to obtain the full appreciation of what the references fairly suggests to one of ordinary skill in the art. Selker I teaches computing and monitoring an acute medical condition, such as cardiac ischemia, that has a sudden and rapid onset over a continuous period of monitoring order to predict the probability of a cardiac event. The teachings of Heemels would not be useful to combine with Selker I because Heemels teaches a cardiac rhythm management device that tracks, outputs, and graphs binned heart rate variability data using a data compression method to minimize memory usage; only 24 hours of data collection is possible, and the object is to provide a current evaluation of a heart condition, not to predict a cardiac event. Selker I would not reasonably be expected to incorporate the teachings of Heemels because the use of data compression is not of any value to

Selker I nor is the limited data collection of only 24 hours of value to Selker I. The objective of Selker I is prediction. In contrast, the objective of Heemels is current state of condition based on a 24-hour period of monitoring.

Similarly, Selker I would not reasonably be combined with Brown because Brown would not be useful to Selker I. Brown teaches an apparatus that is limited to accepting physiological measures from physiological monitoring devices through a physical connection and the objective is to provide such an apparatus that is simple and inexpensive to perform dynamic queries of patients at the initiative and convenience of each patient. Such simplicity, concern for cost, and degree of patient control are not in any way related to the objectives of Selker I. Therefore, there is no motivation or suggestion to combine the teachings of Selker I with Brown.

Second, even when combined by picking and choosing selected parts, the Selker I, Heemels, and Brown patents do not teach or suggest all claim limitations when considered in light of the disclosure of each respective patent. More specifically but not exclusively, the cited references fail to teach or suggest regular recording during an initial observation period for developing a baseline, periodically receiving updated measures regularly recorded after the initial observation period, storage of the initial measures, storage of the subsequent measures, quality of life measures both initial and subsequent, a patient care record for storage of all measures, a patient status indicator based on a baseline of measures, initial quality of life measures, subsequent measures, and subsequent quality of life measures, management of the baseline, and updating of the baseline. Moreover, there is no teaching or suggestion to record and store physiological and quality of life measures during an initial observation period and subsequent to the initial observation period. Selker I, Heemels and Brown teach collecting measures without reference to an initial observation period and not collecting reference physiological and quality of life measures into a reference baseline, per Claims 1, 10, 20, and 25. Thus, Selker I, Heemels and Brown fail to teach or suggest all the claim limitations.

Finally, even if combined, Selker I, Heemels, and Brown would provide a

device for monitoring acute medical conditions based on heart variability data collected by an external physiological monitoring device and not patient monitoring using a reference baseline for use in automated patient care, per Claims 1, 10, 20, and 25. Thus, there would be no reasonable expectation of success when combining Selker I, Heemels and Brown. Since Selker I, Heemels and Brown provide teachings that, when combined, would provide an inoperative result, there would be no suggestion or motivation to combine, particularly in the absence of teachings for storing and using a reference baseline.

Claims 2-5 are dependent on Claim 1 and are patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Similarly, Claims 11-14 are dependent on Claim 10 and are patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Claims 21-23 are dependent on Claim 20 and are patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Claims 26-28 are dependent on Claim 25 and are patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Accordingly, as a *prima facie* case of obviousness has not been shown for Claims 1-5, 10-14, 20-23 and 25-28, withdrawal of the rejection for obviousness under 35 U.S.C. 103(a) is requested.

Claims 7-9 and 16-18 stand rejected under 35 U.S.C. 103(a) as being obvious over Selker I, in view of Heemels et al, and further in view of Brown, and further in view of U.S. Patent No. 4,852,570, to Levine. Applicant traverses the rejection.

As described above with reference to the obviousness rejection of Claims 1-5, 10-14, 20-23, and 25-28, the Selker I, Heemels, and Brown patents, taken as a whole, do not provide a suggestion, motivation, or reason to combine. Similarly, Levine does not provide a suggestion or motivation to combine. Levine teaches a medical process and apparatus for repeatedly obtaining short-term changes in the physiological functioning of an individual as an aid in diagnosing illness and malfunction and in determining longer term changes and trends that are or may be indicative of the onset of a developing adverse condition (Abstract). Physiological

information about an individual is obtained and made available to a physician in a useful form (Col. 2, lines 5-16). A comprehensive series of medical tests are periodically taken of an individual at frequent intervals, and the results are recorded on a small portable medical history card that is intended to be carried by the person tested (Col. 2, lines 17-23). The tests are preferably made using an automatic or semi-automatic apparatus without the presence of an attendant (Col. 2, lines 23-26). The medical history card is intended to be continually carried by the individual (Col. 2, lines 28-30). An individual consults with a physician at long-term interval, such as on an annual basis, for diagnosis (Col. 2, lines 33-45). More specifically, Levine teaches conducting tests using a set of external transducers to monitor the various body functions of a patient during an exercise program; the patient's physiological function is then collected and recorded by the transducers (Col. 10, lines 59-65).

Selker I would not be reasonably combined with Levine when considering the disclosures as a whole to obtain the full appreciation of what the references fairly suggests to one of ordinary skill in the art. Selker I teaches computing and monitoring an acute medical condition, such as cardiac ischemia, that has a sudden and rapid onset over a continuous period of monitoring order to predict the probability of a cardiac event. Levine would not be useful to combine with Selker I because Levine teaches monitoring over a long period of time, approximately one year, at the initiative of an individual. A person of ordinary skill in the art would not reasonably combine Levine with Selker I because of the longer period of time of monitoring in Levine and the level of individual control in Levine. Selker I would require medical data useful for prediction of cardiac events using statistical methods or relevant technology, which is not provided or suggested by Levine.

Claims 7-9 are dependent on Claim 1 and are patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Claims 16-18 are dependent on Claim 10 and are patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Accordingly, as a *prima facie* case of obviousness has not been shown for Claims

7-9 and 16-18, withdrawal of the rejection for obviousness under 35 U.S.C. 103(a) is requested.

Claims 19 and 30 are rejected under 35 U.S.C. 103(a) as being obvious over Selker I, in view of Heemels et al, in view of Brown, and further in view of Levine, and further in view of U.S. Patent No. 6,067,466, issued May 23, 2000, to Selker et al. (Selker II). Applicant traverses the rejection.

As described above with reference to the obviousness rejection of Claims 1-5, 10-14, 20-23, and 25-28, the Selker I, Heemels, Brown, and Levine references fail to provide a suggestion, motivation, or reason to combine. Additionally, all claim limitations are not provided by the combination of Selker I, Heemels, Brown, Levine, and Selker II, even if combined by picking and choosing. Selker II teaches a method for evaluating a medical condition of a patient by monitoring clinical features and using the features to compute a primary probability and a plurality of conditional probabilities of a medical outcome or diagnosis (Abstract; col. 1, lines 57-67). The probabilities are displayed to aid a user in determining whether to administer a diagnostic test to the patient (Col. 2, lines 1-5). The clinical feature is an EKG-related characteristic of the patient (Col. 2, lines 7-8 and 33-34). The patient condition is a cardiac problem (Col. 2, lines 8 and 35). The diagnostic test is one of CK blood test, ETT, stress test, or Sestamibi scanning test. (Col. 2 lines 11-12). A predictive instrument includes a 12-lead electrocardiogram, a waveform analyzer, and a processor module that are used in conjunction with other clinical information entered by a physician through a keyboard to computer a probability that a patient will have a life-threatening condition (Col. 3, lines 26-52).

The Selker I, Heemels, Brown, Levine, and Selker II patents do not teach or suggest all claim limitations when considered in light of the disclosure of each respective patent. More specifically but not exclusively, the cited references fail to teach or suggest regular recording during an initial observation period for developing a baseline, periodically receiving updated measures regularly recorded after the initial observation period, storage of the initial measures, storage of the subsequent measures, quality of life measures both initial and subsequent, a

patient care record for storage of all measures, a patient status indicator based on a baseline of measures, initial quality of life measures, subsequent measures, and subsequent quality of life measures, management of the baseline, and updating of the baseline.

Claim 19 is dependent on Claim 10 and is patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Similarly, Claim 30 is dependent on Claim 25 and is patentable for the above-stated reasons, and as further distinguished by the limitations recited therein. Accordingly, as a *prima facie* case of obviousness has not been shown for Claims 19 and 30, withdrawal of the rejection for obviousness under 35 U.S.C. 103(a) is requested.

The amendment filed August 15, 2003 stands subject to objection for introducing new matter into the disclosure. The alleged new matter has been cancelled. Withdrawal of the objection is requested.

The prior art made of record and not relied upon has been reviewed by the applicant and is considered to be no more pertinent than the prior art references already applied.

Claims 1-5, 7-14, 16-23, 25-28, and 30 are believed to be in condition for allowance. Entry of the foregoing amendments is requested and a Notice of Allowance is earnestly solicited. Please contact the undersigned at (206) 381-3900 regarding any questions or concerns associated with the present matter.

Respectfully submitted,

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